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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,114	08/01/2003	Terence O'Reilly	4-30400B	3640
1095	7590	10/19/2005	EXAMINER	
NOVARTIS CORPORATE INTELLECTUAL PROPERTY ONE HEALTH PLAZA 104/3 EAST HANOVER, NJ 07936-1080			LEWIS, AMY A	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/633,114		O'REILLY ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Amy A. Lewis		1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2005.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 73-203 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 73-203 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 09/233,993.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>10/8/03 &amp; 4/18/05</u>   | 6) <input type="checkbox"/> Other: _____                                    |

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## **DETAILED ACTION**

### ***Status of the Case***

The Amendment, filed 23 March 2005, has been entered into the application. Accordingly, claims 73-203 have been added and claims 1-72 have been cancelled.

Claims 73-203, as filed 23 March 2005, are presented for examination.

### ***Priority***

Acknowledgement is made of Applicant's claim for foreign priority, under 35 U.S.C. § 119(a)-(d), to:

United Kingdom Application No. 9803905, filed on 25 February 1998;  
United Kingdom Application No. 9803907, filed on 26 February 1998;  
United Kingdom Application No. 9805936, filed on 19 March 1998; and  
United Kingdom Application No. 9805937, filed on 19 March 1998.

The certified copies of which were filed in parent application 09/233,993 (now US Patent No. 6,302,838).

### ***Objection to the Specification***

A reference to the prior application(s) must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). A statement reading "This is a continuation of Application No. 09/925119, now US Patent No. 6,635,666, filed 9 August 2001," as well as for all other related applications and their current status, should be entered into the specification. Also, the current status of all nonprovisional parent applications referenced should be included. See 37 CFR 1.78(a) and MPEP § 201.11 part III.

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1) Claims 73-184 and 190-203 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of US Patent No. 6,302,838. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both teach a method of treating a proliferative disease selected from the same specific cancer/tumor types by administering epothilone B. US Patent No. 6,302,838 claims a method of treating the instantly claimed specific cancers: colorectal tumors, genitourinary tumors (which would include ovarian tumors of instant application claims 149 & 193, and bladder cancer of instant application claim 193), lung tumors, prostate tumors, breast tumors, and epidermoid cancer (which includes head and neck cancer of instant application claim 193). U.S. Patent No. 6,302,838 also claims dosing and administration schedules according to the same formulas (Formula I and Formula II), which overlap those of the instant application.

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US Patent No. 6,302,838 also claims that the tumors be refractory to treatment with a member of the taxane class of anti-cancer agents or that the tumor is multi-drug resistant.

2) Claims 73-189 and 193-203 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,635,666. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both teach a method of treating a proliferative disease selected from the same specific cancer/tumor types by administering epothilone B. US Patent No. 6,635,666 claims a method of treating the instantly claimed specific cancers: gastrointestinal tumors (of instant application claims 73 and 185), ovarian cancer (of instant application claims 73, as a type of genitourinary cancer, & 193), head and neck cancer (of instant application claims 112, as a type of epidermoid cancer, & 193), bladder cancer (of instant application claims 73, as a type of genitourinary cancer, & 193), and gastric cancer (of instant application claims 112 & 193). US Patent No. 6,635,666 claims administration schedules according to the same formulas (Formula I and Formula II), which overlap those of the instant application.

3) Claims 73-203 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 73-109 and 154-190 of copending Application No. 11/089269. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim methods of treating cancer by administering epothilone B according to the same dosing and administration schedules calculated by the same formulas (Formula I and Formula II). Both applications also claim that the cancers

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be refractory to treatment with a chemotherapeutic other than epothilone, 5-fluorouracil, an agent of the taxane class of anti-cancer agents, or paclitaxel. It is noted that copending Application No. 11/089269 claims cancer and solid tumors in general, while the instant application claims various specific cancer types, making the instant application claims an obvious variation of the general copending 11/089269 claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 185-203 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 185, 190, 193, and 195 generally recite a method of treatment which comprises the steps of a) identifying a human patient suffering from the claimed disorder, and b) administering to the patient epothilone B. The specification does not describe any means or criteria by which to identify a human subject suffering from any of the claimed disorders (i.e.,

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any of the specifically claimed cancers, tumors, or proliferative diseases). Accordingly, the instant specification fails to provide an adequate written description of a method of treating a proliferative disease and/or the specifically claimed cancers/tumors generally which comprise a step of identifying a human subject suffering from said disorders, and the specification as filed fails to provide adequate written description for any means or criteria by which a person of ordinary skill in the art could diagnose a human subject suffering from the claimed disorders for practicing the instantly claimed method of treatment including diagnosis.

### *Conclusion*

Claims 73-203 are rejected. No claims are allowed.

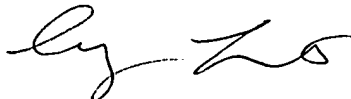
### Contact Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy A. Lewis whose telephone number is (571) 272-2765. The examiner can normally be reached on Monday-Friday, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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